UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

17/MAR/2004

MEMORANDUM

Subject:	Name of Pesticide Product:	Storicide™ II Grain, Bin and Warehouse Insecticide
	EPA File Symbol:	7501-ENE
	DP Barcode:	D297637
	Decision No.:	330296
	PC Code:	059102 Chlorpyrifos-methyl
		097805 Deltamethrin
From:	Rick J. Whiting	RJW
	Technical Review Branch	SCN
	Registration Division (7505C)	
To:	Akiva Abramovitch, PM Team 07	
	Branch	
	Registration Division (7505C)	
Applicant:	GUSTAFSON LLC	
	1400 Preston Road, Suite 400	
	Plano, TX 75093	

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
059102 Chlorpyrifos-methyl	21.60%
097805 Deltamethrin	3.70%
Inert Ingredient(s):	100.0%
Total:	100.0%

This product contains aromatic hydrocarbon solvents.

ACTION REQUESTED:

The Product Manager requests: "Please review tox of new product."

BACKGROUND: GUSTAFSON LLC has submitted a six pack of acute toxicity studies in support of registration of Storicide™ II Grain, Bin and Warehouse Insecticide, EPA File Symbol 7501-ENE. The studies were conducted at Product Safety Labs, Dayton, New Jersey with assigned MRID numbers 461408-01 to -06.

RECOMMENDATIONS: The six studies have been reviewed and are classified as Acceptable. The acute toxicity profile for Storicide™ II Grain, Bin and Warehouse Insecticide, EPA File Symbol 7501-ENE, is as follows:

Acute oral toxicity	II	Acceptable	MRID 46140801
Acute dermal toxicity	IV	Acceptable	MRID 46140802
Acute inhalation toxicity	III	Acceptable	MRID 46140803
Primary eye irritation	I	Acceptable	MRID 46140804
Primary skin irritation	II	Acceptable	MRID 46140805
Dermal sensitization	Positive	Acceptable	MRID 46140806

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 007501-00202

PRODUCT NAME: Storicide™ II Grain, Bin and Warehouse Insecticide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

SPANISH SIGNAL WORD: PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Contains Petroleum Distillate.

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Do not get on skin or on clothing. Wear long-sleeved shirt and long pants, socks, chemical-resistant footwear, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Viton, Barrier Laminate, Viton, Selection Category F, G). If the Selection Category F, G gloves do not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance glove selection chart that will provide adequate protection. Avoid breathing spray mist.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. When mixing and loading wear a chemical resistant apron.

First Aid:

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything to an unconscious person.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move the person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:
- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

NOTE TO PHYSICIAN: May pose an aspiration pneumonia hazard. Contains petroleum distillate.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Acute Oral Toxicity Up and Down Procedure in Rats: Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: 14408, P320/UDP. Unpublished study prepared by Product Safety Labs. November 14, 2003. MRID No. 46140801

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46140801), seven female Sprague-Dawley rats (Age: 9 weeks; Weight: 178-203 g; Source: Ace Animals, Inc. Boyertown, PA) were given a single oral dose of Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid) using the Up and Down Procedure (OECD Guideline 325). "Based on an estimate LD_{50} supplied by the Sponsor, (2,800 mg/kg), an initial dose of 890 mg/kg was administered to one healthy female rat by oral gavage. Following the Up and Down procedure, six additional females were tested at dose levels of 89 or 280 mg/kg." Individual animal body weights were recorded prior to dosing and again on Days 7 and 14 after dosing or after death. Clinical signs of toxicity were made during the first several hours post-dosing and at least once daily thereafter for up to 14 days after dosing. A gross necropsy examination was performed on all animals.

Oral LD_{50} Females is estimated to be 150.4 mg/kg.

Based on the estimated LD_{50} in females, Storicide II Grain, Bin, and Warehouse Insecticide is classified as EPA Toxicity Category II.

The three animals dosed with 89 mg/kg survived the exposure to the test material. All animals gained weight over the 14-day observation period. Clinical signs observed in these animals included hypoactivity, abnormal gait and ano-genital staining. All clinical signs were resolved by Day 2. No gross pathological findings were observed.

The three animals dosed with 280 mg/kg died with four hours of dosing. Clinical signs noted prior to death included hypoactivity and abnormal gait. Gross necropsy revealed discoloration of the intestines.

The one animals dosed with 890 mg/kg died within three hours of dosing. No clinical signs were noted prior to death. Gross necropsy revealed discoloration of the intestines.

This acute oral study is classified as Acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

"Individual animals were dosed as follows:

Main Test

Dosing Sequence	Animal No.	Dose level (mg/kg)	24 hour Outcome	14 Day Outcome
1	1311	890	D	D
2	1373	280	D	D
3	1385	89	S	S
4	1435	280	D	D
5	1463	89	S	S
6	1540	280	D	D
7	1562	89	S	S

S = survival D = death

"Based on an estimate LD_{50} supplied by the Sponsor, (2,800 mg/kg), an initial dose of 890 mg/kg was administered to one healthy female rat by oral gavage. Following the Up and Down procedure, six additional females were tested at dose levels of 89 or 280 mg/kg."

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Tuesday, March 16, 2004, 9:29:05 AM
Data file name: work.dat
Last modified: 3/11/2004 9:58:58 AM

Test/Substance: 7501-ENE Storcide II Grain, Bin and Warehouse Insecticide
Test type: Main Test
Limit dose (mg/kg): 2000
Assumed LD50 (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 2000, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	1311	890	X	X
2	1373	280	X	X
3	1385	89	O	O
4	1435	280	X	X
5	1463	89	O	O
6	1540	280	X	X
7	1562	89	O	O

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

WARNING:
Please review the data for accuracy.
Starting the Main Test above the likely LD50 will induce bias toward the starting dose. See OECD Guideline 425.

Stopping criteria met: 5 reversals in 6 tests.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
89	3	0	3
280	0	3	3
890	0	1	1
All Doses	3	4	7

Statistical Estimate based on long term outcomes:

Estimated LD50 = 150.4 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 89 to 280.

Statistics - Acute Oral Toxicity (Guideline 425) Statistical Program (Westat, version 1.0, May 2001) was used for all data analyses including: dose progression selections, stopping criteria determinations and/or LD_{50} and confidence limit calculations.

A. Mortality - as noted in table.

B. Clinical observations - Clinical signs observed in the three animals dosed with 89 mg/kg included hypoactivity, abnormal gait and ano-genital staining. All clinical signs were resolved by Day 2.

Clinical signs observed prior to death in the three animals dosed with 280 mg/kg included hypoactivity and abnormal gait.

No clinical signs were observed in the one animal dosed with 890 mg/kg.

C. Gross Necropsy - No gross necropsy findings were observed in the animals dosed with 89 m/kg. Discoloration of the intestines was observed in the animals dosed with 280 and 890 mg/kg/

D. Reviewer's Conclusions: Agree with study authors.

E. Deficiencies - None.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Acute Dermal Toxicity Study in Rats - Limit Test: Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: 14409, P322. Unpublisbed study prepared by Product Safety Labs. November 14, 2003. MRID No. 46140802

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46140802), five young adult Sprague-Dawley rats/sex (Age: 8-9 weeks; Weight: 250-265 g males; 180-190 g females; Source: Ace Animals, Inc., Boyertown, PA) were dermally exposed to a single application of Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid) at 5000 mg/kg bw for 24 hours. The test material was applied evenly over a dose area of approximately 2 inches x 3 inches (10% of body surface). Individual body weights were recorded prior to test material application and again on Day 7 and 14. Test animals were observed for clinical signs of toxicity and mortality during the first several hours after application and at least once daily thereafter. A gross necropsy examination was performed on all animals at the time of scheduled euthanasia.

Dermal LD_{50} Males => 5000 mg/kg bw
Dermal LD_{50} Females => 5000 mg/kg bw
Dermal LD_{50} Combined => 5000 mg/kg bw

Based on the lack of mortality at the limit dose, Storicide II Grain, Bin, and Warehouse Insecticide is classified as EPA Toxicity Category IV.

All animals survived and gained weight during the study. Clinical signs observed included skin irritation (erythema and edema), irregular respiration and reduced fecal volume. Except for the skin irritation which cleared by Day 9, the other clinical signs were resolved by Day 4. No gross pathological findings were observed.

This acute dermal study is classified Acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Statistics - The dermal LD_{50} was calculated using the limit dose.

A. Mortality - as noted in table.

B. Clinical observations - All animals survived and gained weight during the study. Clinical signs observed included skin irritation (erythema and edema), irregular respiration and reduced fecal volume. Except for the skin irritation which cleared by Day 9, the other clinical signs were resolved by Day 4.

C. Gross Necropsy - No gross pathological findings were observed.

D. Reviewer's Conclusions: Agree with the study author.

E. Deficiencies - None.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Acute Inhalation Toxicity Study in Rats: Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: 14410, P330. Unpublished study prepared by Product Safety Labs. November 14, 2003. MRID No. 46140803

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46140803), 5/sex of Sprague-Dawley rats (Age: 8-10 weeks; Weight: 261-317 g males; 180-247 females; Source: Ace Animals, Inc. Boyertown, PA) were exposed whole body via the inhalation route to Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid) for up to 4 hours at concentrations of 0.53 and 2.58 mg/L. Individual animal body weights were recorded prior to test material exposure and again on Days 7 and 14 or after death. The animals were observed for clinical signs of toxicity at least every 30 minutes during exposure and at least once daily thereafter for up to 14 days. A gross necropsy examination was performed on all animals.

LC_{50} Males and Females > 0.53 mg/L and < 2.58 mg/L

Based on the mortality observed at 2.58 mg/L and the lack of mortality at 0.53 mg/L, Storicide II Grain, Bin, and Warehouse Insecticide is classified as EPA Toxicity Category III.

All animals exposed to 0.53 mg/L survived and gained body weight during the study. Clinical signs observed during exposure included ocular and nasal discharge, abnormal respiration and hunched posture. Clinical signs observed after exposure included irregular respiration, hunched posture, hypoactivity and reduced fecal volume. All animals had recovered from these symptoms by Day 2. No gross pathological findings were observed.

All animals exposed to 2.58 mg/L died before the end of the 4-hour exposure period. Clinical signs observed during exposure included ocular and nasal discharge, abnormal respiration, abnormal posture and hypoactivity. Gross necropsy revealed dark red, edematous lungs.

This acute inhalation study is classified as Acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Actual Conc. (Gravimetric/ Analytical) (mg/L)	MMAD µm	GSD µm	Mortality/Number Tested		
				Males	Females	Combined
3.53	0.53	2.3	1.80	0/5	0/5	0/10
20.80	2.58	2.5	1.89	5/5	5/5	10/10

Test Atmosphere / Chamber Description:

Exposure Level (mg/L)	0.53	2.58
Chamber Volume:	150 L	150 L
Airflow:	45.8 LPM	45.7 LPM
Temperature:	21-22 °C	21-22 °C
Relative Humidity:	48-75%	50-82%
Time to Equilibrium:	15.1 min.	15.1 min.

Test atmosphere concentration - From Page 10 of study: Gravimetric samples were withdrawn at five (2.58 mg/L) or six (0.53 mg/L) intervals from the breathing zone of the animals during each exposure.

Particle size determination - From Page 10 of study: An eight-stage Andersen impactor was used to assess the particle size distribution of the test atmosphere. Samples were withdrawn from the breathing zone of the animals at two intervals during each exposure.

A. Mortality - as noted in table.

B. Clinical observations - All animals exposed to 0.53 mg/L survived and gained body weight during the study. Clinical signs observed during exposure included ocular and nasal discharge, abnormal respiration and hunched posture. Clinical signs observed after exposure included irregular respiration, hunched posture, hypoactivity and reduced fecal volume. All animals had recovered from these symptoms by Day 2.

All animals exposed to 2.58 mg/L died before the end of the 4-hour exposure period. Clinical signs observed during exposure included ocular and nasal discharge, abnormal respiration, abnormal posture and hypoactivity.

C. Gross Necropsy - No gross pathological findings were observed in animals exposed to 0.53 mg/L.

Gross necropsy revealed dark red, edematous lungs in animals exposed to 2.58 mg/L.

D. Reviewer's Conclusions: Agree with study author.

E. Deficiencies - None.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Primary Eye Irritation Study in Rabbits: Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: P324, 14411. Unpublished study prepared by Product Safety Labs. November 5, 2003. MRID No. 46140804

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46140804), 0.1 ml of Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid) was instilled into the right eye of three young adult female New Zealand White rabbits (Source: Robinson Services, Inc., Clemmons, NC). The untreated left eye served as a control. The first animal tested exhibited signs of distress immediately following instillation. Subsequently, two drops of ocular anesthetic (Tetracaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the treated and control eye of the remaining two animals prior to instillation of the test material. Ocular irritation was evaluated in accordance with Draize et at. (1944) at 1, 24, 48 and 72 hours and a 4, 7, 10, 14 and 21 days post-instillation.

Based on the corneal opacity still observed in one animal at Day 21, Storicide II Grain, Bin, and Warehouse Insecticide is classified as EPA Toxicity Category I.

Corneal opacity (score 1) was observed in all three eyes from 1 hour to Day 17 and in one eye at Day 21. Iritis (score 1) was observed in all three eyes from 1 hour to Day 7 and in two eyes till Day 14. Conjunctival redness (score 3 and 2) was observed in three eyes from 1 hour to Day 14. Conjunctival chemosis (score 3 and 2) was observed in all three eyes from 1 hour to Day 7. Conjunctival discharge (score 3 and 2) was observed in all three eyes from 1 hour to Day 4 and in 2/3 eyes on Day 7. All conjunctival irritation was resolved by Day 17.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

Observations	Number "positive"/number tested									
	Hours				Days					
	1	24	48	72	4	7	10	14	17	21
Corneal Opacity	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3	1/3
Iritis	3/3	3/3	3/3	3/3	3/3	3/3	2/3	2/3	0/3	0/3
Conjunctivae:										
Redness*	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3	0/3	0/3
Chemosis*	3/3	3/3	3/3	3/3	3/3	3/3	0/3	0/3	0/3	0/3
Discharge*	3/3	3/3	3/3	3/3	3/3	2/3	0/3	0/3	0/3	0/3
Severity of Irritation - Mean Score	26.0	39.3	38.0	37.3	34.0	31.3	21.7	19.0	10.3	1.7

*Score of 2 or more required to be considered "positive."

A. **Observations** - Corneal opacity (score 1) was observed in all three eyes from 1 hour to Day 17 and in one eye at Day 21. Iritis (score 1) was observed in all three eyes from 1 hour to Day 7 and in two eyes till Day 14. Conjunctival redness (score 3 and 2) was observed in three eyes from 1 hour to Day 14. Conjunctival chemosis (score 3 and 2) was observed in all three eyes from 1 hour to Day 7. Conjunctival discharge (score 3 and 2) was observed in all three eyes from 1 hour to Day 4 and in 2/3 eyes on Day 7. All conjunctival irritation was resolved by Day 17.

B. **Reviewer's Conclusions:** Agree with the study author.

C. **Deficiencies** - None.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Primary Skin Irritation Study in Rabbits: Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: 14412, P326. Unpublished study prepared by Product Safety Labs. November 5, 2003. MRID No. 46140805.

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46140805), 2 male and 1 female young adult New Zealand White rabbits (Age: Not reported; Source: Davidson's Mill Farm, South Brunswick, NJ) were dermally exposed to 0.5 mL of Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid). The test material was applied to one 6 cm^2 intact dose site on each animal and covered with a 1 inch x inch gauze pad. The pad and entire trunk of each animal were then wrapped with semi-occlusive tape to avoid dislocation of the pad. After 4 hours of exposure to the test material, the pad was removed and the test sites were cleaned of residual test material. Individual dose sites were scored according the Draize (1944) scoring system at approximately 1, 24, 48 and 72 hours and at 7, 10 and 14 days after patch removal.

Based on the moderate to severe erythema (score 3) observed in 3/3 animals and the slight edema (score 2) observed in 3/3 animals at 72 hours, Storicide II Grain, Bin, and Warehouse Insecticide is classified as EPA Toxicity Category IV. PDII is 3.4.

One hour after patch removal, all three sites exhibited very slight erythema (score 1). By 72 hours, moderate to severe erythema (score 3) and slight edema (score 2) was observed. By Day 14, all three sites still exhibited well-defined erythema (score 2). All edema had been resolved by Day 14.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal No.	Sex	Hours After Patch Removal				Days		
		1	24	48	72	7	10	14
10430	M	1/0	2/2	2/2	3/2	2/2	2/1	2/0
10431	F	1/0	2/1	2/1	3/2	2/2	2/0	2/0
10432	M	1/0	2/2	2/2	3/2	3/2	2/0	2/0
Severity of Irritation - Mean Score		1.0	2.7	3.7	5.0	4.3	2.3	2.0

A. Observations - One hour after patch removal, all three sites exhibited very slight erythema (score 1). By 72 hours, moderate to severe erythema (score 3) and slight edema (score 2) was observed. By Day 14, all three sites still exhibited well-defined erythema (score 2). All edema had been resolved by Day 14.

B. Results - PDII = 3.4

C. Reviewer's Conclusions - Agree with study author.

D. Deficiencies - None.

Reviewer: Rick J. Whiting **Date: March 17, 2004**
Product Manager (EPA): 07

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406, 429

TEST MATERIAL: Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

CITATION: Moore, G. (2003) Dermal Sensitization Study in Guinea Pigs (Buehler Method): Storcide II Grain, Bin, and Warehouse Insecticide. Project Number: 14413, P328. Unpublished study prepared by Product Safety Labs. November 21, 2003. MRID No. 46140806

SPONSOR: GUSTAFSON LLC, 1400 Preston Road, Suite 400, Plano, TX 75093

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 46140806) with Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid), 30 young adult male Hartley albino guinea pigs (Source: Elm Hill Breeding Labs, Chlemsford, MA) were tested using the Buehler method (1980). Once a week for three weeks, 0.4 ml of a 75% w/w mixture of the test material in mineral oil was topically applied to the left side of twenty test animals using an occlusive 24 mm Hill Top Chamber. After the 6-hour exposure period, the chambers were removed and the test sites were cleaned of any residual test material. Twenty-eight days after the first induction dose, a challenge dose of the test material at its highest non-irritating concentration (HNIC, determined to be 25% w/w mixture in mineral oil) was applied to a naive site on each guinea pigs. A naive control group of ten animals was treated with the test substance at challenge only. Approximately 24 and 48 hours after each induction and challenge dose, the animals were scored for erythema. The procedures were validated using alpha-Hexylcinnamaldehyde (HCA) as the positive control substance.

Very faint to moderate erythema (score 0.5-3) was observed at all test sites during the induction phase. Ten of the twenty test animals were observed with faint erythema (score 1) 24 hours following the challenge application while the remaining animals were observed with very faint erythema (score 0.5). At 48 hours, 5 animals were observed with faint erythema and 15 animals were observed with very faint erythema. Very faint erythema (score 0.5) was observed in 2/10 naive control test sites 24 hours following challenge application. Similar irritation was observed at 1 site through 48 hours.

Based on the findings above, Storicide II Grain, Bin, and Warehouse Insecticide is considered a contact sensitizer.

This study is classified as Acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 406, 429) in the Guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE

A. Induction - Once a week for three weeks, 0.4 ml of a 75% w/w mixture of the test material in mineral oil was topically applied to the left side of twenty test animals using an occlusive 24 mm Hill Top Chamber. After the 6-hour exposure period, the chambers were removed and the test sites were cleaned of any residual test material. Approximately 24 and 48 hours after each induction, the animals were scored for erythema.

B. Challenge - Twenty-eight days after the first induction dose, a challenge dose of the test material at its highest non-irritating concentration (HNIC, determined to be 25% w/w mixture in mineral oil) was applied to a naive site on each guinea pigs. Approximately 24 and 48 hours after the challenge dose, the animals were scored for erythema.

C. Naive Controls - A naive control group of ten animals was treated with the test substance at challenge only. Approximately 24 and 48 hours after the challenge dose, the animals were scored for erythema.

II. RESULTS and DISCUSSION:

A. Reactions and duration - Very faint to moderate erythema (score 0.5-3) was observed at all test sites during the induction phase. Ten of the twenty test animals were observed with faint erythema (score 1) 24 hours following the challenge application while the remaining animals were observed with very faint erythema (score 0.5). At 48 hours, 5 animals were observed with faint erythema and 15 animals were observed with very faint erythema. Very faint erythema (score 0.5) was observed in 2/10 naive control test sites 24 hours following challenge application. Similar irritation was observed at 1 site through 48 hours.

B. Positive control - Results were appropriate with HCA study to validate test procedures.

C. Reviewer's Conclusions: Agree with study author.

D. Deficiencies - Initial individual body weights were not collected prior to the study initiation due to a technician oversight (from page 11 of study). Although this information is required by the study protocol, this deviation did not have an impact on the study's conclusion.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D297637
2. **PC CODE:** 059102 Chlorpyrifos-methyl & 097805 Deltamethrin
3. **CURRENT DATE:** March 17, 2004
4. **TEST MATERIAL:** Storicide II Grain, Bin, and Warehouse Insecticide (Chlorpyrifos-methyl: 21.6% w/w; Deltamethrin: 3.7% w/w; Lot No. TAR108:94-1; amber colored, clear free-flowing liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat Product Safety Laboratories 14408, P320/UDP / 11-14-03	46140801	LD_{50} = 150.4 mg/kg (females)	II	A
Acute dermal toxicity / rat Product Safety Laboratories 14409, P322 / 11-14-03	46140802	LD_{50} => 5000 mg/kg (males and females)	IV	A
Acute inhalation toxicity / rat Product Safety Laboratories 14410, P330 / 11-14-03	46140803	LC_{50} > 0.53 mg/L and < 2.58 mg/L (males and females)	III	A
Primary eye irritation / rabbit Product Safety Laboratories P324, 14411 / 11-05-03	46140804	Corneal opacity observed in 1 animal at Day 21	I	A
Primary dermal irritation / rabbit Product Safety Laboratories 14412, P326 / 11-05-03	46140805	Moderate to severe erythema & slight edema in 3/3 animals at 72 hours	II	A
Dermal sensitization / guinea pig Product Safety Laboratories 14413, P328 / 11-21-03	46140806	Considered to be a contact sensitizer	—	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable